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V5

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 08/704,159 | 08/28/96 | WILLIAMS J | OPHD-02304 |

HM12/0815

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| EXAMINER | |
|---|---|
| NAVARRO, A | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | 22 |

**DATE MAILED:** 08/15/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 08/704,159 | Applicant(s) Williams et al |
|---|---|---|
| | Examiner Mark Navarro | Group Art Unit 1645 |

☒ Responsive to communication(s) filed on *May 17, 2000*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *10-14 and 25-41* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *10-14 and 25-41* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

Applicant's amendment filed May 17, 2000 (Paper Number 21) has been received and entered. New claims 32-41 have been added, consequently claims 10-14 and 25-41 are pending in the instant application.

### *Claim Rejections - 35 USC § 112*

1. The rejection of claims 10-14 and 25-31 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained. Additionally this rejection is applied to newly submitted claims 32-41.

Applicant's are asserting that the Examiner has cited the quote of Ellis *et al* from page 571 completely out of context. Applicant's assert that Ellis describes using recombinant DNA technology to prepare a large quantity of a single protein, such that this protein can be used as a vaccine. Applicant's conclude that therefore this reference is in direct contrast to the Examiner's contention that it is unclear whether a single protein... will elicit protective immunity. Applicant's further assert that the specification provides ample guidance in determining which portions of these toxins would produce neutralizing vaccines. Applicant's cite Examples 23, 36, and 42 which test a "portion (e.g., C fragment) of the given toxin using a mouse model which is the art accepted method for detection of botulinal toxins in body fluids and for evaluation of anti-

botulinal antibodies. Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's arguments are not found to be fully persuasive in view of the teaching of Ellis *et al* that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies." Ellis is not cited to set forth that it is impossible to vaccinate with a single protein or portion thereof, rather that it is unpredictable which proteins are capable of eliciting protective antibodies. The art is full of proteins which have been administered in vivo and resulted in an immunogenic response, however this response is not necessarily protective. A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Furthermore, Applicant's assertions of using a mouse model which is the art accepted method for detection of botulinal toxins in body fluids is not commensurate in scope with claims that recite a soluble and neutralizing vaccine. Again mere antigenic response as would be detected using the art accepted method for detection of botulinal toxins is not the threshold required for immunoprotection as recited in the claims.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, makes clear that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

For reasons of record in Paper Number 19 as well as those recited above this rejection is maintained.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner

can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

August 12, 2000